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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	585-017-84	9844

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KATTEN MUCHIN ROSENMAN LLP
525 WEST MONROE STREET
CHICAGO, IL 60661-3693

EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005 and 20 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5,00

DETAILED ACTION

Amendment Entry

1. Applicant's amendment April 20, 2005 and response filed January 25, 2005 are acknowledged and have been entered. Claims 1, 3, 6, 7, and 10 have been amended. Currently, claims 1-6 and 9-11 remain pending and are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

Rejections Maintained

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6 and 9-11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is being maintained for reasons of record.

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-6 and 9-11 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for regulating body weight of rats by feeding them a fat-containing diet and an amount of liposome-encapsulated immunoglobulin against lipase effective to reduce body weight gain, does not reasonably provide enablement for a method wherein the liposome-encapsulated immunoglobulin against lipase is effective to inhibit body-weight gain in any and all animals, as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is being maintained for reasons of record.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 and 9-11 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is being maintained for reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has improper antecedent basis problem in reciting, "feeding to an animal". Change to "feeding to the animal" for proper antecedent basis.

Claim 6 lacks antecedent support in reciting, "said diet".

Claim 10 lacks antecedent support in reciting, "said diet".

Response to Arguments

7. Applicant's arguments filed January 25, 2005 have been fully considered but they are not persuasive.

A) Applicant submits that by amending the claims to be limited to avian antibodies, adequate written support is provided by the specification for the recitation of "effective to inhibit body-weight gained due to consumption of said diet". Applicant also argues that the recitation of "effective to inhibit body-weight gained due to consumption of said diet" is adequately supported by the specification which provides description of "decreased body weight gain per unit of food".

In response, Applicant's arguments are not on point. The recitation of "effective to inhibit body-weight gained" which means "to prevent weight gain" does not encompass the metes and bounds of a more lenient capacity to "effectively decrease body weight gained per unit of food", which is provided by the specification. Additionally, amending the claims to recite "avian antibodies" does not appear to change the scope of the claims which recite that the food composition is effective to inhibit body-weight gained, whereas the specification only supports that the food composition effectively can decrease body weight gained in rats. Accordingly, the new matter rejection based on the recitation of "effective to inhibit body-weight gained due to consumption of said diet" is being maintained.

B) Applicant argues that the scope of enablement problem has been resolved by amending the claims to recite "avian antibodies" which have been shown to be effective in the specification.

In response, amending the claims to recite "avian antibodies" does not appear to resolve the fact that the specification is only enabled for rats that have been fed a fat-

containing diet having an amount of liposome-encapsulated avian immunoglobulin against lipase effective to reduce body weight gained in rats.

C) Applicant argues that the written description problem has been resolved by amending the claims to recite "avian antibodies" which have been shown to be effective in the specification.

In response, amending the claims to recite "avian antibodies" does not appear to resolve the fact that the specification fails to describe how avian antibodies are able to cause the active site of any mammalian lipase antigen to be inhibited since immunological binding of antilipase antibodies to lipase does not equate to blocking the catalytic epitope of lipase antigen. Therefore, the capability to generate anti-lipase antibodies from lipase of avian origin that can act upon lipase antigen in any and all animals, to react or bind in such a way that its catalytic epitope is blocked, either in the GI tract or systemically in the plasma and inhibit weight gain, remain to be an unpredictable task. Antibodies generated from avian lipase sources which appear to react to lipase in rats, may not necessarily have specificity for and cross-reactivity with any other lipase of mammalian species, i.e. human or canine species, so as to inhibit body weight gained.

D) Applicant argues that claim 1 does not require "totally" inhibiting body weight gain and hence, claim 1 should not be interpreted as such.

In response, the recitation of "effective to inhibit body-weight gained" implies prevention from any amount of weight gained; hence, it does not encompass the metes and bounds of a more lenient capacity to "effectively decrease body weight gained per unit of food", which is provided by the specification. The specification appears to only show that there is reduction of weight gained, rather than inhibition or prevention of weight gain which results from consumption of the claimed food composition.

Prior Art

8. Currently, claims 1-6 and 9-11 are clear of the prior art of record.

9. For reasons aforementioned, no claims are allowed.

10. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on April 20, 2005 prompted the new grounds of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
July 7, 2005

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
7/8/05